

Music interventions in operative treatment of funnel chest

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22918

Source

Nationaal Trial Register

Brief title

IMPECT

Health condition

Pectus excavatum

Sponsors and support

Primary sponsor: University Medical Center

Source(s) of monetary or material Support: Erasmus University Medical Center

Intervention

Outcome measures

Primary outcome

Main parameter is the experienced level of pain, assessed with self-report on the Visual Analogue Scale (VAS) expressed in millimetres.

Secondary outcome

- Morphine equivalence daily dose/kilogram (MEDD/kg) and total dosage of other analgesia:
- Score on State-Trait-Anxiety-Inventory questionnaire (STAI) and Health related quality of life (HRQoL):
- Physiologic measurements, including blood pressure, heart rate and respiratory rate:
- Complications, like post-operative ileus (n of days), nausea/vomiting (n of days and also anti-emetics used), pruritus:
- Length of hospital stay (n of days):
- Economic evaluation

Study description

Background summary

Rationale: This study will investigate the effects of listening to a recorded music intervention prior, during and after surgical pectus excavatum treatment. Multiple studies have found music interventions may reduce post-operative pain, anxiety and distress in patients undergoing a surgical procedure. Since surgical pectus excavatum treatment is a highly painful as well as distressing procedure, this durable non-toxic method could be a welcome intervention. In this study, we will investigate the hypothesis that music interventions prior, during and after pectus excavatum surgery will result in less postoperative pain and distress.

Objective: The main objective of this study is to investigate the role of recorded music prior, during and after surgery as an additive treatment modality in reducing the level of pain. Secondary objectives are effects of music on the use of analgesics, on anxiety and distress, vital parameters, minor postoperative complications, quality of life and care-costs.

Study design: This study will be performed as a parallel randomised controlled intervention trial.

Study population: The research will take place in patients in the age of 12 to 18 years old, who are operated for the diagnosis pectus excavatum by the Nuss-procedure in the participating centres.

Intervention: The intervention group will receive several music interventions, delivered by headphone, prior and during surgery, as well as post-operatively. The control group will only receive headphones during surgery but no music will be played.

Main study parameters/endpoints: The main study endpoint is self-reported pain-scores defined on the Visual Analogue Scale (VAS). Other endpoints are the amount of morphine used in the first three days postoperative as calculated by the Morphine Equivalent Dose Daily/ kilogram (MEDD/kg), levels of anxiety and distress, Quality of Life and physiological parameters such as heart rate, saturation and blood pressure.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The use of music as intervention has no known deleterious effects on patients. Safety precautions will be taken to limit the volume of the music on headphones during surgery. Patients in all study arms will receive standard perioperative care. Post-operative care and pain control will be performed according to standard protocols in the different centres of research. Burden includes the completion of several questionnaires. Measurements of vital signs will be collected from normal care data. No extra site visits will

be necessary for participation in this study besides the regular check ups at the outpatient clinic. This research is performed in minors from 12 years and older as well as adults, as this operation is mainly done in the age of 12 to 16 years, however it is also performed in adults.

Study objective

Music interventions will reduce anxiety and pain in patients undergoing a nuss bar procedure due to pectus excavatum

Study design

At outpatient clinic, during hospitalization until the third day of hospitalization, 3 months postoperative at the outpatient clinic

Intervention

Music interventions pre-, intra- and postoperatively

Contacts

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Eligibility criteria

Inclusion criteria

- Age 12 – 18 years
- Scheduled for primary PE repair according to the Nuss-procedure with either one or multiple bars
- Postoperatively, initial placement of a thoracic epidural or both thoracic epidural and patient-controlled analgesia system
- Good knowledge of the Dutch language, by both patients and parents
- Written informed consent. Additional written informed consent by parents or legal guardian is only necessary for children under the age of 16 years.

Exclusion criteria

- Hearing impairment
- Secondary PE surgery or other prior thoracic surgery
- Known severe mental or psychiatric disorder
- Known impaired communication with patient and parents as collected
- Presence of chronic pain syndrome: ongoing pain lasting longer than 3 months or ongoing pain lasting longer than the reasonably expected healing time for the involved tissues)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2018
Enrollment:	170
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 22-02-2018

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6863
NTR-old	NTR7041
Other	METC EMC : 2016543

Study results